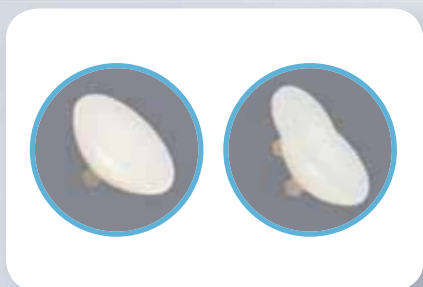




The HemiCAP® Shoulder Restoration Systems

restore the articular surface geometry of the humeral head and preserve functional structures using an innovative 3 dimensional mapping system and a contoured articular resurfacing implant.



Chapter One

Hemi Shoulder Arthroplasty

Chapter Two

Inlay Glenoid Replacement

Chapter Three

Joint Preserving Total Shoulder Arthroplasty

Anterior Deltopectoral Approach

1. Beachchair position (tilt back to 45 degree angle).
2. Short deltopectoral incision (from coracoid tip to pectoralis major insertion).
3. This incision is utilitarian and can be converted to an extensile approach if necessary.
4. Develop skin flaps over pectoralis & deltoid.
5. Develop deltopectoral interval.
 - a. The cephalic vein may go either medially or laterally. Lateral retraction of the cephalic vein can be beneficial because it preserves the venous outflow from the deltoid.
 - b. Identify coracoid tip.
 - c. Identify pectoralis major insertion.
6. Release subdeltoid and subacromial adhesions. Abducting the shoulder in order to relax the deltoid facilitates this step.
7. Retract the deltoid and pectoralis major muscles. This step is facilitated by the use of a blunt, multi-pronged self-retaining retractor.
8. Identify and develop the lateral border of the conjoined tendon. This step is assisted by flexion of the shoulder, which relaxes the conjoined tendon & facilitates exposure.
9. Retract the conjoined tendon medially. Take care to not injure the musculocutaneous nerve. A blunt, non self-retaining retractor under the conjoined tendon facilitates exposure while minimizing risk to the nerve.
10. Remove bursa from atop the subscapularis insertion.
11. Identify the anterior humeral circumflex vessels, which define the inferior aspect of the subscapularis. As needed, a 90 degree pediatric clamp is a useful tool to isolate the vessels. If necessary, a suture can be used to ligate the vessels.
12. Identify and protect axillary nerve. The axillary nerve lies deep to the anterior humeral circumflex vessels and superficial to the subscapularis muscle at the level of the glenoid. A rubber vessel loop can be used to protect/isolate the axillary nerve, if necessary.
13. Incise the subscapularis. Use of a needle tip electrocautery 1 cm lateral to the musculotendinous junction facilitates this step.
 - a. Patients with anterior-inferior instability may be candidates for capsular shift and/or Bankart repair. In such cases, begin the subscapularis incision inferiorly and proceed superiorly in order to best differentiate the tendon from the underlying capsule.
 - b. Alternatively, the subscapularis and capsule can be incised in one layer.
 - c. Alternatively, the lesser tuberosity may be osteotomized with a sharp, 1 inch straight osteotome. This will allow bone to bone healing at the conclusion of the procedure.

14. Place #2 sutures using a Mason-Allen configuration into the edge of the subscapularis to help retract the tendon and for definitive repair at the conclusion of the procedure.
 - a. A medium Cobb elevator and/or Metzenbaum scissors help to bluntly develop the layer between the subscapularis and the joint capsule. It is important to separate the subscapularis and the capsule medial to the joint line in order to address (if necessary) a Bankart lesion.
15. Release the rotator interval capsule between the upper border of the subscapularis and the anterior edge of the supraspinatus.
16. Incise the glenohumeral joint capsule along the anatomic neck with electrocautery.
17. If necessary, place a blunt "Cobra" or Hohman retractor between the axillary nerve and subscapularis/capsule in order to protect the axillary nerve.
18. Release the glenohumeral capsule from its insertion on the anatomic neck of the humerus anteriorly and inferiorly. External rotation and flexion of the shoulder facilitates capsular release and improves humeral head exposure.
19. Release the capsule completely off the anatomic neck until adequate exposure of the humeral head defect is achieved.
 - a. Posterior humeral head defects can be successfully addressed with the Arthrosurface® HemiCAP® implant using an anterior deltopectoral exposure. Inferior capsular release

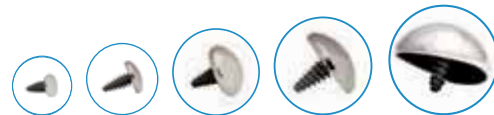


from the anatomic neck of the humerus is an important step. Take care to release the capsule directly off the bone in order to minimize risk to the axillary nerve. Blunt retractors (i.e. Cobra or Hohman) placed between the inferior capsule and the axillary nerve can also minimize neurological injury.

20. Place a humeral head retractor (i.e. Fukuda) to evaluate the glenoid and check for a Bankart lesion.
21. Address any glenoid pathology as indicated.
22. Insert Arthrosurface® HemiCAP® implant as indicated.
23. Repair glenohumeral joint capsule and subscapularis as indicated.
24. Closure utilizing accepted practices.

Chapter One (Pages 5-16)

Hemi Shoulder Arthroplasty



"Our measurements show that if a variation in size is needed in the design of the prosthesis, it is the humeral component that should have **the greatest range in size.**"

*JP Iannotti, JP Gabriel, SL Schneck, BG Evans, and S Misra.
The normal glenohumeral relationships. An anatomical study of one hundred and forty shoulders.
J Bone Joint Surg Am. 1992;74:491-500.*

Chapter Two (Pages 17-22)

Inlay Glenoid Replacement



"The success of shoulder arthroplasty surgery has been limited by a common complication: glenoid implant loosening. Eccentric loading of the glenoid due to migration of the humeral head is considered to be the major cause of glenoid loosening and is referred to as the rocking-horse phenomenon. Glenoid implant loosening may cause pain, limitation of function and the need for complicated revision surgery. **Mechanical tests and finite element analysis support the concept of "inset" glenoid fixation in minimizing the risk of glenoid loosening.**"

Gunther SB, Lynch TL, O'Farrell D, Calyore C, Rodenhouse A. Finite element analysis and physiologic testing of a novel, inset glenoid fixation technique. J Shoulder Elbow Surg. 2012 Jun;21(6):795-803.

Chapter Three (Pages 23-30)

Total Shoulder Arthroplasty



"Resurfacing more closely **restored the geometric center** of the humeral head than hemiarthroplasty did, with less eccentric loading of the glenoid. Compared with hemiarthroplasty, humeral resurfacing may limit eccentric glenoid wear and permit better function because the glenohumeral joint biomechanics and the moment arms of the rotator cuff and the deltoid muscle are **restored more closely to those of the intact condition.**"

*Garth Hammond, MD1; James E. Tibone, MD2; Michelle H. McGarry, MS3; Bong-Jae Jun, PhD3; Thay Q. Lee, PhD3
The Journal of Bone & Joint Surgery. 2012; 94:68-76*



Hemi Shoulder Arthroplasty



25 mm



30 mm



35 mm



40 mm



OVO★

KEY FEATURES:

Over 40 anatomically matched implant convexities

AVN, locked dislocators, traumatic lesions, & OA

Clinically proven published peer reviewed data

Description

The HemiCAP® Contoured Articular Prosthetic incorporates an articular resurfacing component and a taper post component that mate together via a morse taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Materials

Articular Resurfacing Component:	Cobalt-Chromium Alloy (Co-Cr-Mo)
Undersurface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)

Indications

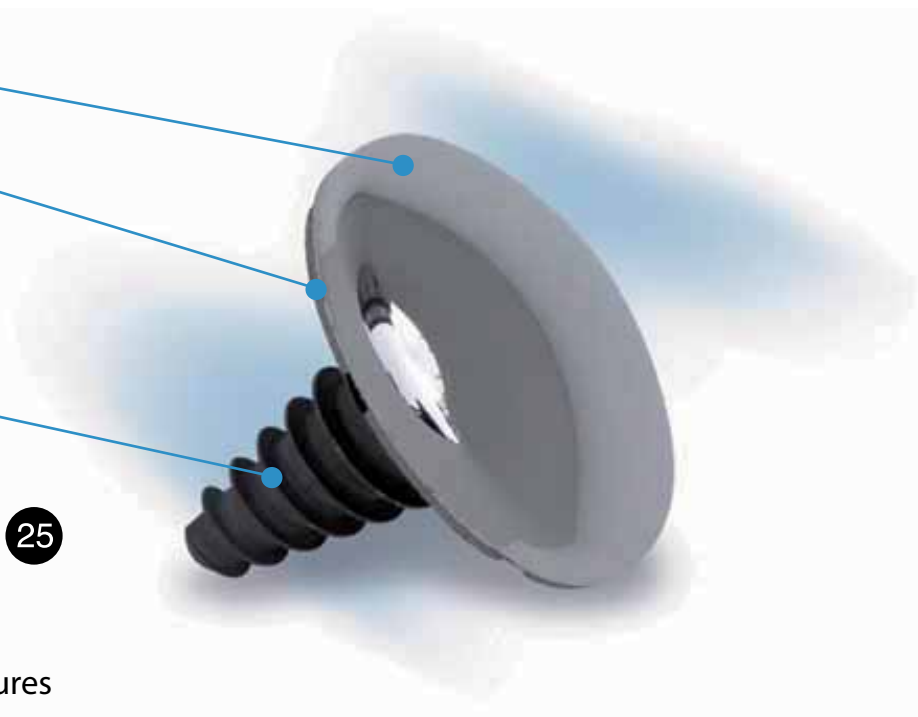
For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

Patient selection factors to be considered include:

- 1) Need to obtain pain relief and improve function.
- 2) Patient age as a potential for early-age revision of total joint arthroplasty.
- 3) Patient overall well-being, including ability and willingness to follow instructions and comply with activity restrictions.

HemiCAP® System Components

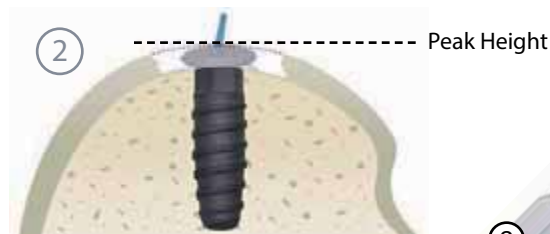
- Cobalt Chrome Component
- Ti Plasma Spray Undercoating
- Morse Taper:
Interlocks the two components
- Titanium Fixation Component
(Cannulated, Bead blasted)
- 5 Diameters **ovo** **40** **35** **30** **25**
- Over 40 Different Convexities in
Symmetrical and Asymmetrical Curvatures



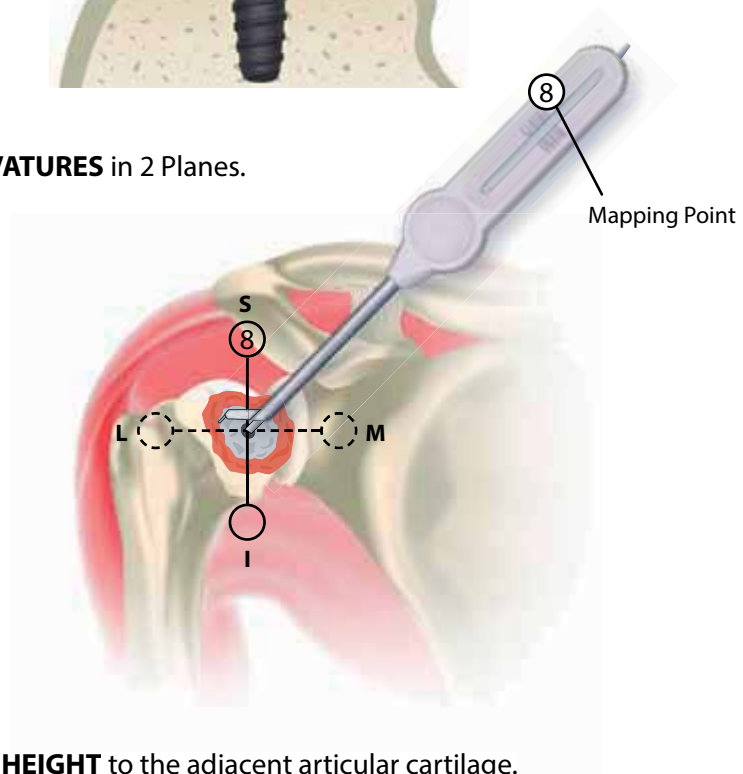
Arthrosurface® 3-Dimensional Mapping

This technique allows the surgeon to **intraoperatively place an implant with precision** in terms of diameter, peak height and recreation of the natural S/I and M/L curvatures.

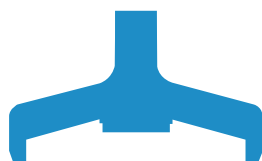
1. The Drill Guide determines the best **DIAMETER** for coverage of defect and establishes perpendicularity.
2. The Trial Cap sets the **PEAK** height of the original joint surface.



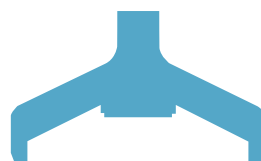
3. The Contact Probe **MAPS** the Surface **CURVATURES** in 2 Planes.



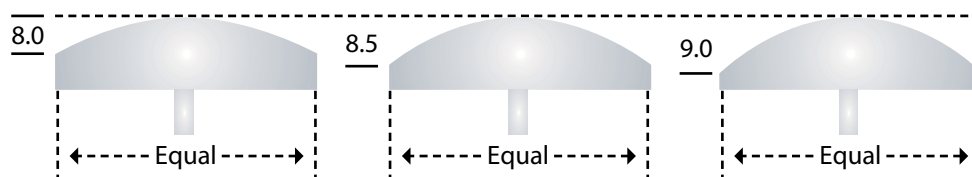
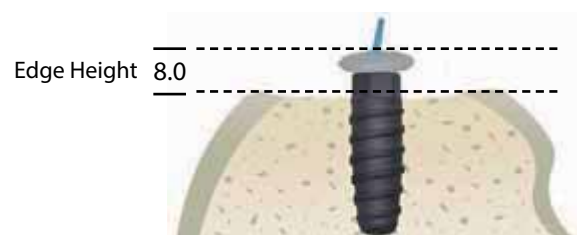
4. The Reamers and Sizing Trials set the **EDGE HEIGHT** to the adjacent articular cartilage.



**Flatter
Humeral Head**



**More Curved
Humeral Head**



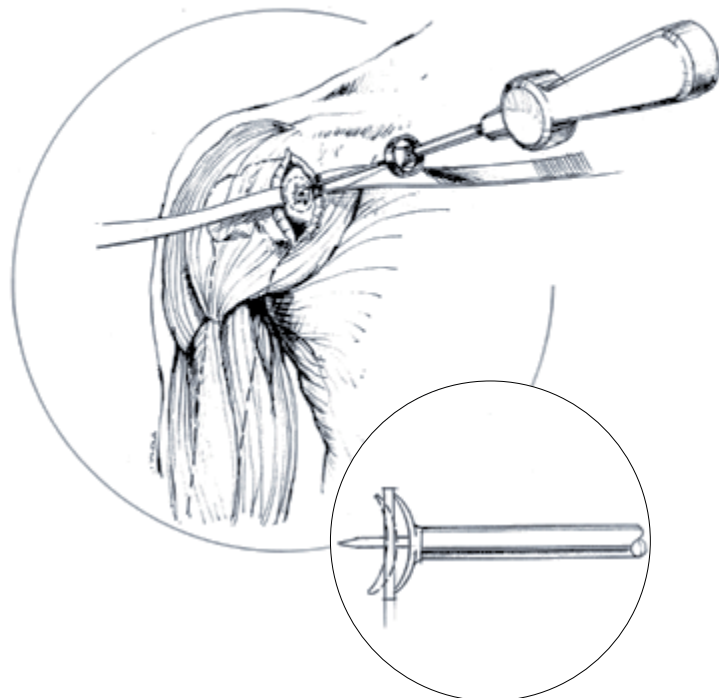
Surgical Technique (Hemi Shoulder Arthroplasty)

1. Use the **Drill Guide** to locate the axis normal to the articular surface and central to the defect. Choose the correct **Drill Guide** diameter sufficient to circumscribe the defect. Confirm the appropriate **Articular Component** diameter by matching it to the **Drill Guide** diameter. Place the **Guide Pin** into a cannulated powered drill and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** through the **Drill Guide** into the bone making sure that it is central to the defect.

*Note: It is important to verify that the **Drill Guide** is seated on the curved surface such that four points of contact are established on the articular surface. A normal axis and correct **Articular Component** diameter are necessary for proper implant fit.*



Drill Guide



2. Place the **Step Drill** over the **Guide Pin** and drill until the proximal shoulder of the **Step Drill** is flush with the articular surface. Tap the hole to the etched depth mark on the **Tap**.



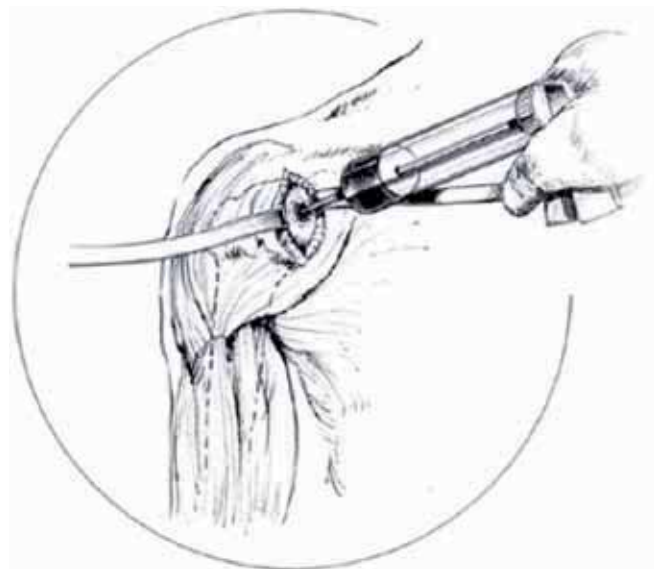
Step Drill



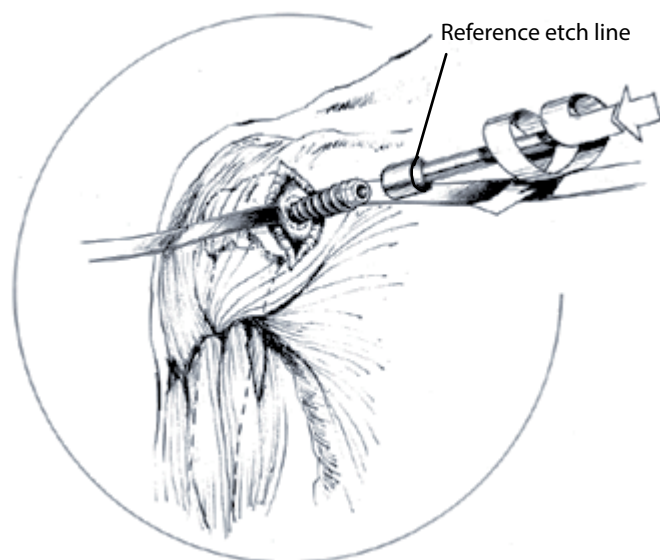
Tap



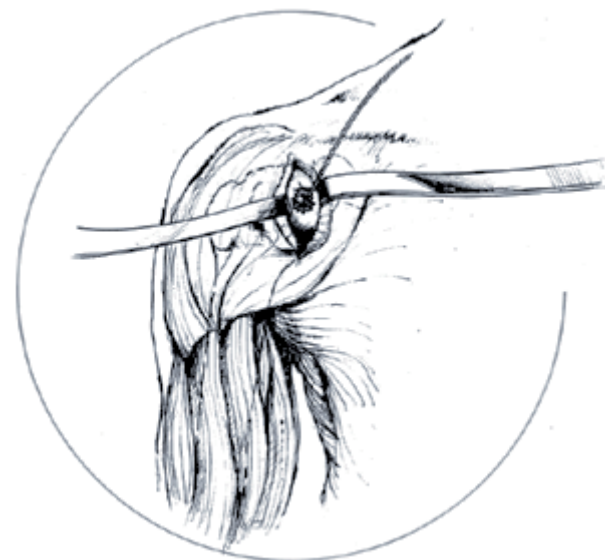
3. Prior to inserting the **Taper Post**, thoroughly cleanse the pilot hole of any debris and inject the cement in a retrograde fashion from the end of the hole upwards.



4. Place the **Driver** onto the **Taper Post** over the **Guide Pin** and advance the **Taper Post** until the line on the **Driver** is flush with the height of the original articular cartilage level.



5. Remove the **Guide Pin**. Clean the taper in the **Taper Post** with the **Taper Cleaner**. Place the **Trial Cap** into the **Taper Post** to confirm the correct depth of the **Taper Post**. The peak height of the **Trial Cap** must be flush or slightly below the existing articular cartilage surface to avoid the **Articular Component** from being placed proud or above the surface of the defect. Adjust depth if needed using the **Driver** to rotate the **Taper Post** (rotate clockwise to advance and counterclockwise to retract). Remove the **Trial Cap**.



Trial Cap

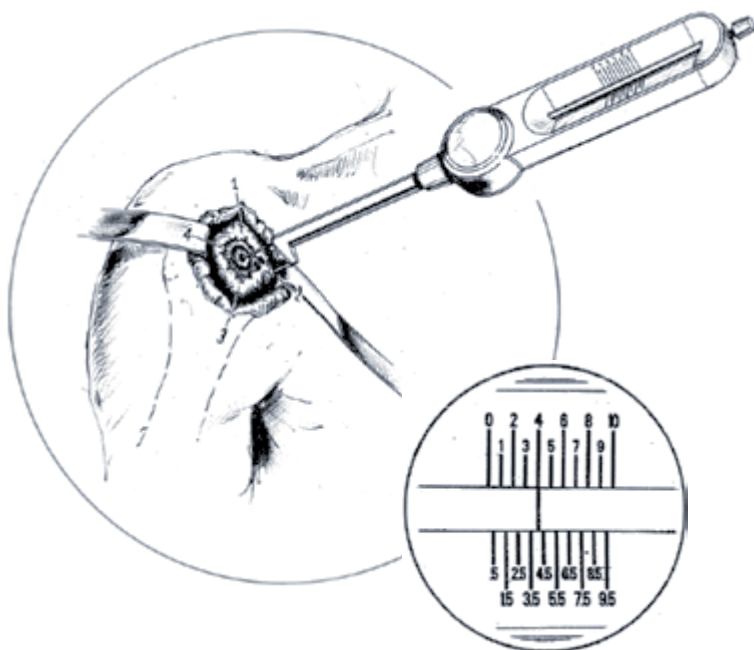


6. Place the **Centering Shaft** into taper of the **Taper Post**. Place the **Contact Probe** over the **Centering Shaft** and rotate around the **Centering Shaft**. Read the **Contact Probe** to obtain offsets at four indexing points (superior/inferior and medial/lateral) and mark each of the identified offsets on the appropriate **Sizing Card**. Select appropriate **Articular Component** using the **Sizing Card**.

Centering Shaft (colored end up)



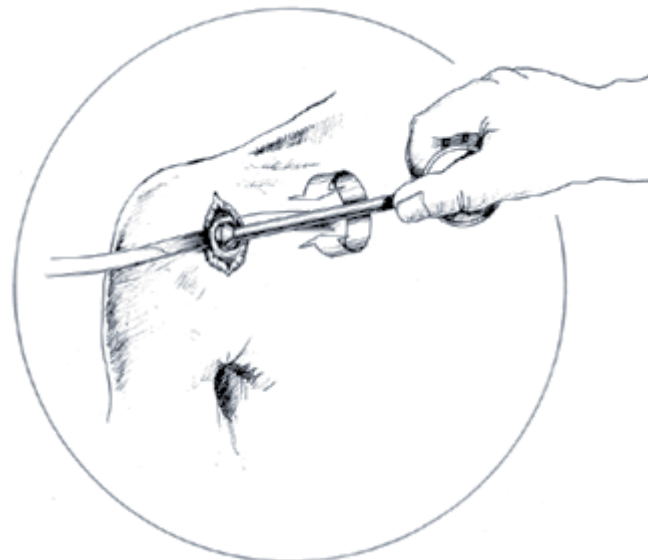
Contact Probe



7. Remove the **Centering Shaft** and replace with the **Guide Pin**. Advance the **Circle Cutter** onto the articular surface by twisting the **Circle Cutter** back and forth avoiding any bending of the **Guide Pin**. Score the articular cartilage down to subchondral bone.



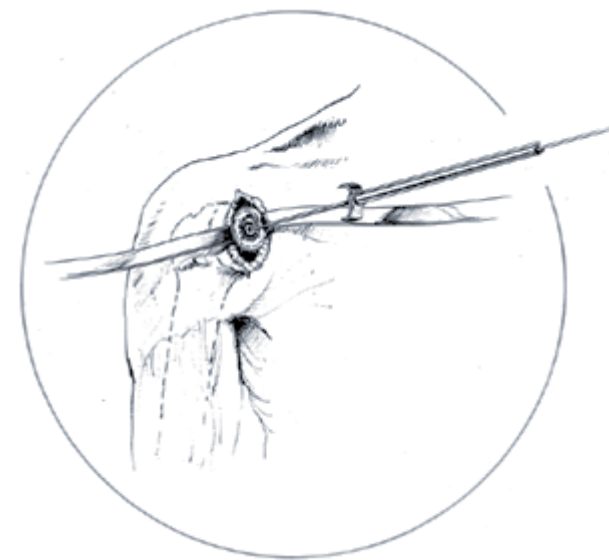
Circle Cutter



8. Choose the appropriate **Surface Reamer** based on the offsets. Confirm selection by matching the color code on the **Articular Component** package with the colored band on the **Surface Reamer** shaft. Drill the **Surface Reamer** over the **Guide Pin** until it contacts the top surface on **Taper Post**. Make sure not to bend the **Guide Pin** during drilling as it may result in **Articular Component** malalignment. Begin rotation of **Surface Reamer** prior to contact with bone to prevent chipping of articular rim.



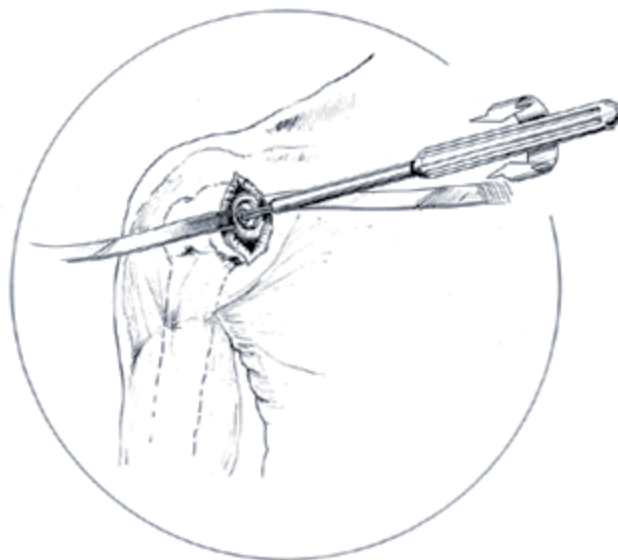
Surface Reamer



9. Remove the **Guide Pin**. Clean the **Taper Post** with the **Taper Cleaner** and remove any debris from the surrounding implant bed.



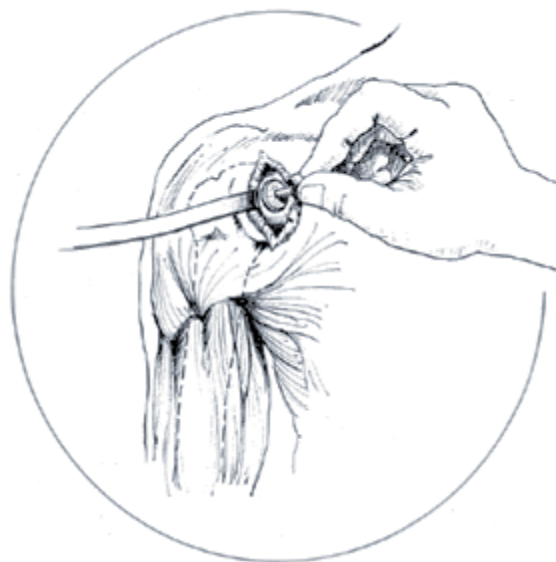
Taper Cleaner



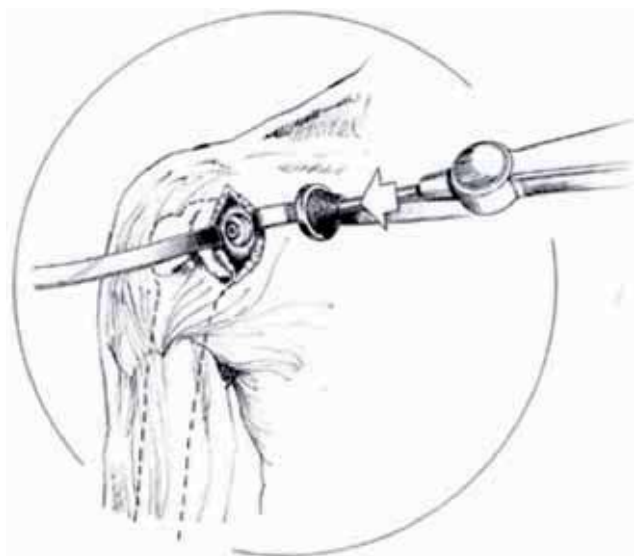
10. Place the **Sizing Trial** into the defect that matches the offset profile of the chosen **HemiCAP® Articular Component**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the edge of the articular cartilage, ream with the next appropriate sized reamer and use the matching **Sizing Trial**. **Sizing Trials** must match **Surface Reamer's** offset size.



Cap Caddy (only for 25/30 mm)



11. Before placing the **Articular Component** on the **Implant Holder**, make sure that sufficient suction is present to hold the device on the distal suction cup. Align the **Articular Component** on the **Implant Holder**. For non-spherical **Articular Components**, orient the etch marks on the back of the **Articular Component** with the etch mark on the handle of the **Implant Holder**. Align the **Articular Component** with the appropriate offsets. Insert into taper of the **Taper Post**.

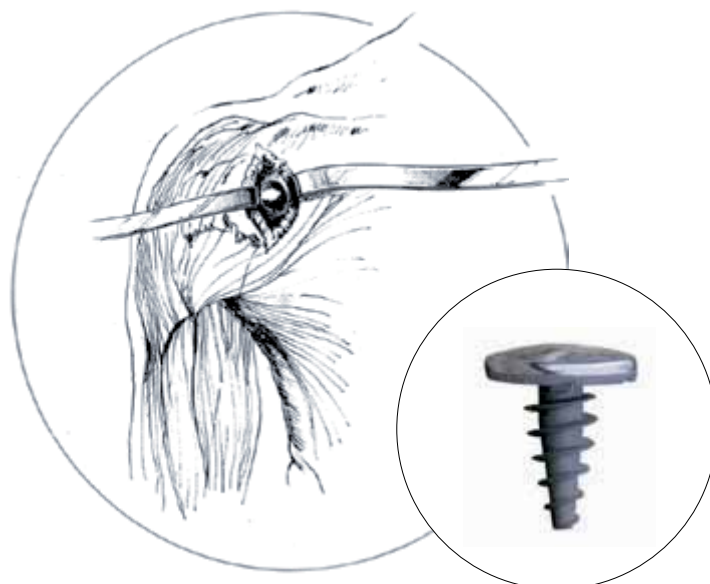
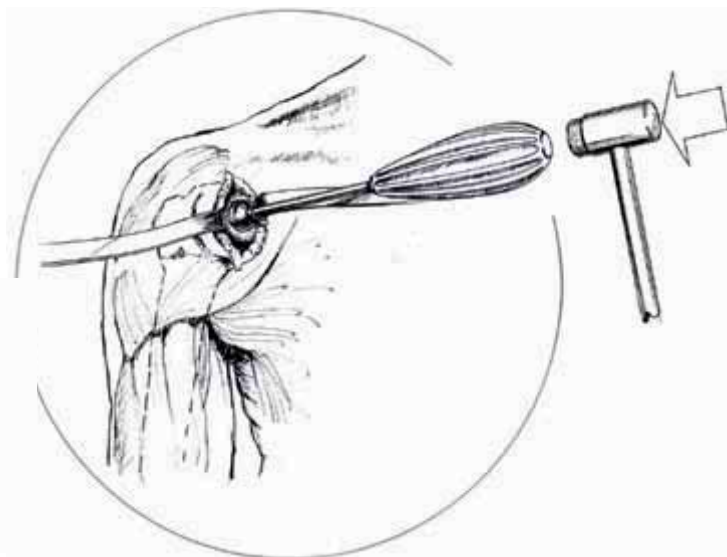


Implant holder

12. Use a slight tap on the **Impactor** to seat the **Articular Component**. Progressively tap the **Impactor** until the **Articular Component** is firmly seated on the bone.



Impactor



Sizing Cards (Hemi Shoulder Arthroplasty)

arthrosurface
Humeral Head

Sizing Card

1. Maximum SI _____

Maximum ML

2. Select 40mm HemiCAP™ offset values
If no match is found, use the next highest offset value

- 8.0 mm x 8.0 mm
- 8.0 mm x 9.0 mm
- 8.5 mm x 8.5 mm
- 9.0 mm x 9.0 mm
- 9.0 mm x 10.0 mm
- 9.5 mm x 9.5 mm
- 10.0 mm x 10.0 mm
- 10.0 mm x 11.0 mm
- 10.5 mm x 10.5 mm
- 11.0 mm x 11.0 mm
- 11.0 mm x 12.0 mm
- 11.5 mm x 11.5 mm
- 12.0 mm x 12.0 mm

3. Select 40mm Surface Reamer size
Choose the Surface Reamer that matches the highest offset value. Confirm with the color code on the HemiCAP™ articular component package.

40

P/N 3001-1040 Rev A

arthrosurface

Sizing Card

1. Maximum SI _____

Maximum ML

2. Select 35mm HemiCAP™ offset values
If no match is found, use the next highest offset value

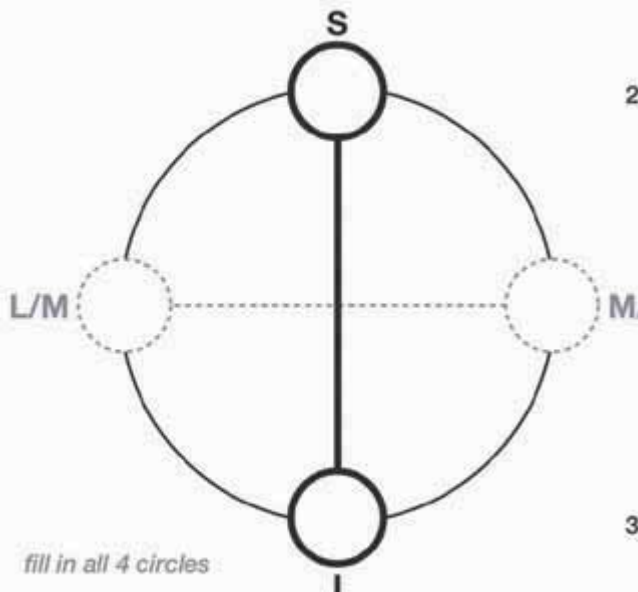
- 6.0 mm x 6.0 mm
- 6.0 mm x 7.0 mm
- 6.5 mm x 6.5 mm
- 7.0 mm x 7.0 mm
- 7.0 mm x 8.0 mm
- 7.5 mm x 7.5 mm
- 8.0 mm x 8.0 mm
- 8.0 mm x 9.0 mm
- 8.5 mm x 8.5 mm
- 9.0 mm x 9.0 mm
- 9.0 mm x 10.0 mm
- 9.5 mm x 9.5 mm

3. Select 35mm Surface Reamer size
Choose the Surface Reamer that matches the highest offset value. Confirm with the color code on the HemiCAP™ articular component package.

35

P/N 3001-1035 Rev B

Sizing Cards (Hemi Shoulder Arthroplasty)



fill in all 4 circles

30

1. Maximum SI _____

Maximum ML _____

2. Select 30mm HemiCAP® offset values

If no match is found, use the next highest offset value

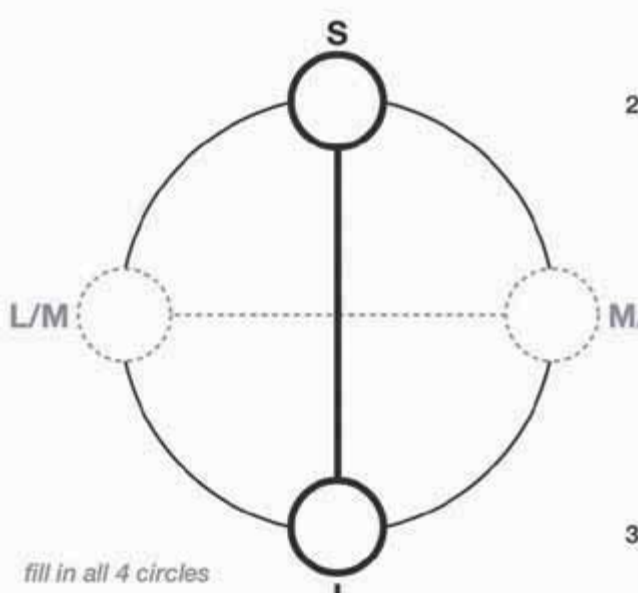
- 4.5 mm x 4.5 mm
- 5.0 mm x 5.0 mm
- 5.5 mm x 5.5 mm
- 6.0 mm x 6.0 mm
- 6.5 mm x 6.5 mm
- 7.0 mm x 7.0 mm

3. Select 30mm Surface Reamer size

Choose the Surface Reamer that matches the highest offset value. Confirm with the color code on the HemiCAP® articular component package.

Sizing Card

P/N 1001-1030 Rev D



fill in all 4 circles

25

1. Maximum SI _____

Maximum ML _____

2. Select 25mm HemiCAP® offset values

If no match is found, use the next highest offset value

- 2.5 mm x 2.5 mm
- 3.0 mm x 3.0 mm
- 3.5 mm x 3.5 mm
- 4.0 mm x 4.0 mm
- 4.5 mm x 4.5 mm
- 5.0 mm x 5.0 mm

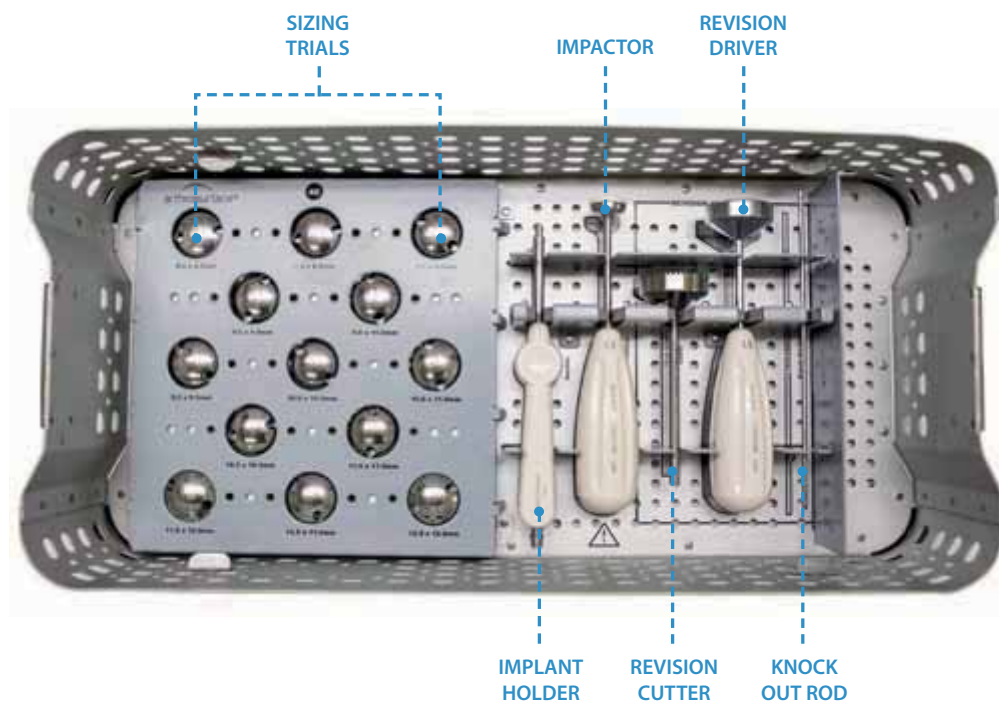
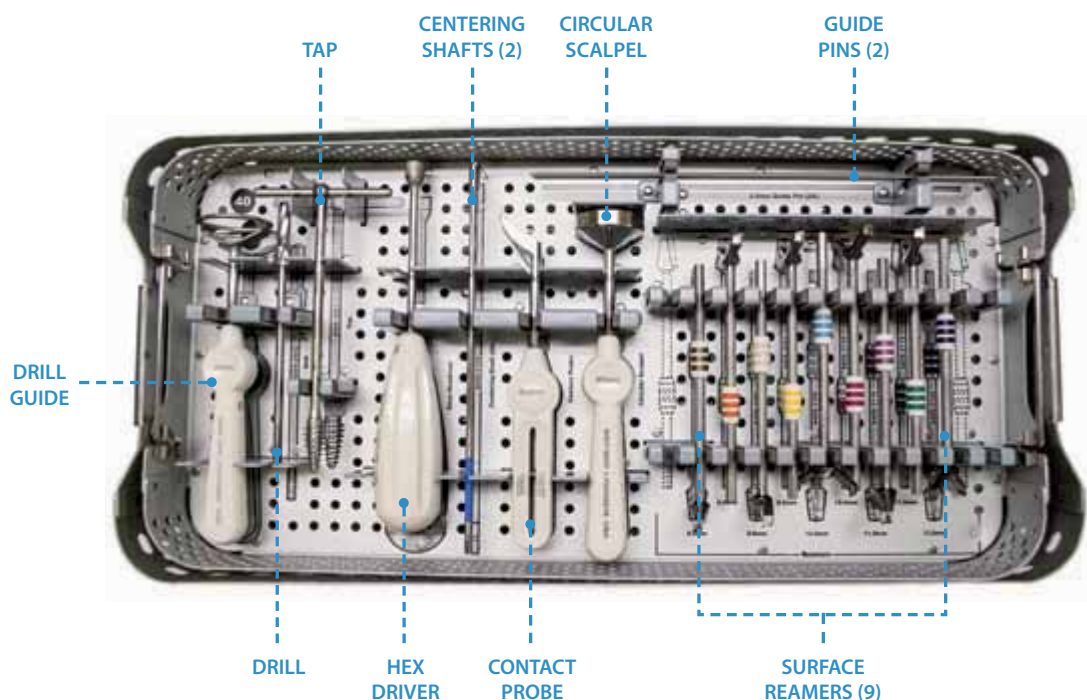
3. Select 25mm Surface Reamer size

Choose the Surface Reamer that matches the highest offset value. Confirm with the color code on the HemiCAP® articular component package.

Sizing Card

P/N 1001-1025 Rev D

Instrumentation (Hemi Shoulder Arthroplasty)



System Catalog (Hemi Shoulder Arthroplasty)

Instrumentation System

8000-4000	Instrument Kit, 40mm includes 40mm Sizing Trials
8000-3000	Instrument Kit, 35mm includes 35mm Sizing Trials
6000-3000	Instrument Kit (6000-2530), 25/30mm and 25/30mm Sizing Trials in Cap Caddy (6000-0500)
8000-5000	Instrumentation Kit, Ovo includes Ovo Sizing Trials
8007-1200	2.5mm Guide Pin (each) for 35mm, 40mm, & Ovo Implants (sterile)
8007-1205	2.5mm Guide Pin (5 pack) for 35mm, 40mm, & Ovo Implants (non-sterile)
6007-1200	2.0mm Guide Pin (each) for 25mm and 30mm Implants (sterile)
6007-1205	2.0mm Guide Pins (5 pack) for 25mm and 30mm Implants (non-sterile)

Taper Post (Fixation Components)

8135-1875	13.7mm x 31mm (for 40mm only)
8135-0032	13.5mm x 31mm (for 35mm only)
6125-0035	12.5mm x 35mm (for 25mm & 30mm only)
6105-0028	10.5mm x 28mm (for 25mm & 30mm only)
8156-0032	15.6mm x 32mm (for Ovo only) includes 2.5mm guide wire, 2.0mm short guide pins and taper cleaner

Ovo Humeral Articular Components

8H02-4642	46mm x 42mm Offset
8H02-4844	48mm x 44mm Offset
8H02-5046	50mm x 46mm Offset
8H02-5248	52mm x 48mm Offset
8H02-5450	54mm x 50mm Offset
8H02-5652	56mm x 52mm Offset
8H02-5854	58mm x 54mm Offset

40mm Articular Components

8402-8080	8.0mm x 8.0mm Offset
8402-8090	8.0mm x 9.0mm Offset
8402-8585	8.5mm x 8.5mm Offset
8402-9090	9.0mm x 9.0mm Offset
8402-9010	9.0mm x 10.0mm Offset
8402-9595	9.5mm x 9.5mm Offset
8402-1010	10.0mm x 10.0mm Offset
8402-1011	10.0mm x 11.0mm Offset
8402-0505	10.5mm x 10.5mm Offset
8402-1111	11.0mm x 11.0mm Offset
8402-1112	11.0mm x 12.0mm Offset
8402-1515	11.5mm x 11.5mm Offset
8402-1212	12.0mm x 12.0mm Offset

35mm Articular Components

8352-6060	6.0mm x 6.0mm Offset
8352-6070	6.0mm x 7.0mm Offset
8352-6565	6.5mm x 6.5mm Offset
8352-7070	7.0mm x 7.0mm Offset
8352-7080	7.0mm x 8.0mm Offset
8352-7575	7.5mm x 7.5mm Offset
8352-8080	8.0mm x 8.0mm Offset
8352-8090	8.0mm x 9.0mm Offset
8352-8585	8.5mm x 8.5mm Offset
8352-9090	9.0mm x 9.0mm Offset
8352-9010	9.0mm x 10.0mm Offset
8352-9595	9.5mm x 9.5mm Offset

30mm Articular Components

8302-0045	4.5mm x 4.5mm Offset
8302-0050	5.0mm x 5.0mm Offset
8302-0055	5.5mm x 5.5mm Offset
8302-0060	6.0mm x 6.0mm Offset
8302-0065	6.5mm x 6.5mm Offset
8302-0070	7.0mm x 7.0mm Offset

25mm Articular Components

8252-0025	2.5mm x 2.5mm Offset
8252-0030	3.0mm x 3.0mm Offset
8252-0035	3.5mm x 3.5mm Offset
8252-0040	4.0mm x 4.0mm Offset
8252-0045	4.5mm x 4.5mm Offset
8252-0050	5.0mm x 5.0mm Offset



Inlay Glenoid Replacement^{*}



Single



Double

KEY FEATURES:

Partial or Full Inlay Glenoid virtually eliminates overstuffing

Glenoid bone preservation permits future onlay options

Inlay design is stable and anatomic to avoid loosening

Off-Axis preparation avoids head removal

^{*} The HemiCAP^{GRS} glenoid component is currently not available in all markets.

Description

The HemiCAP® Contoured Articular Prosthetic incorporates an articular resurfacing component and a taper post component that mate together via a morse taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

The HemiCAP^{GRS} glenoid component is intended to interface and articulate with the humeral component when both articular surfaces of the joint are affected.

Materials

Glenoid Component: Ultra High Molecular Weight Polyethylene (UHMWPE)

Indications

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

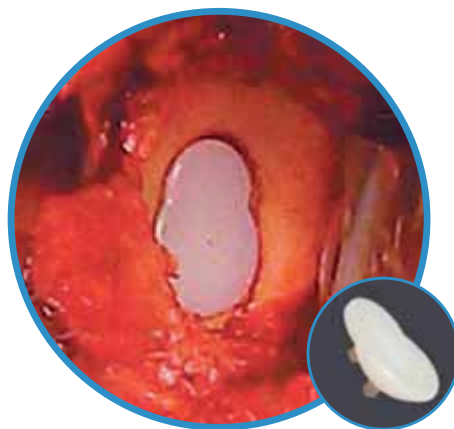
HemiCAP® System Components

- Ultra High Molecular Weight Polyethylene (UHMWPE)
- Inlay design
- Labrum preserving
- Two offset choices per component



Single

Partial Glenoid Component

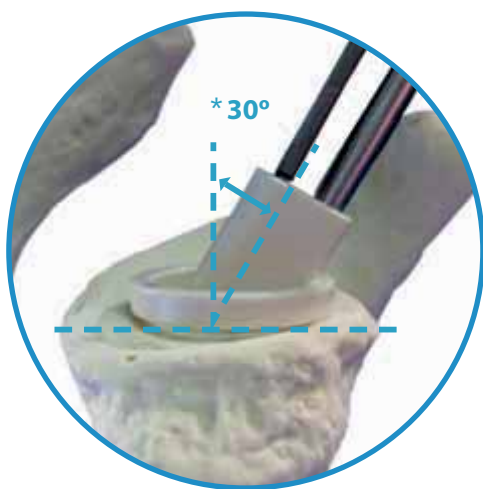


Double

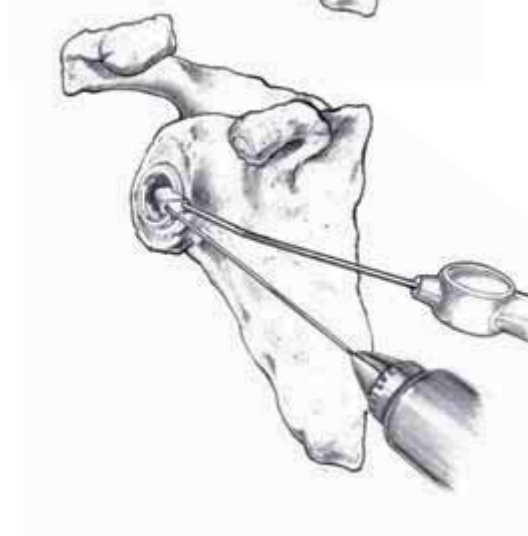
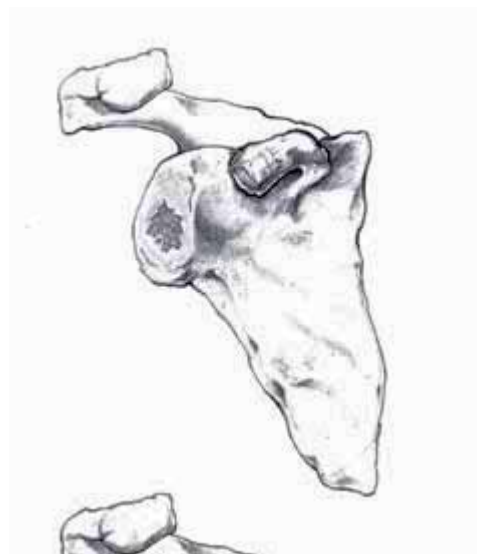
Full Glenoid Component

Surgical Technique (Inlay Glenoid Replacement)

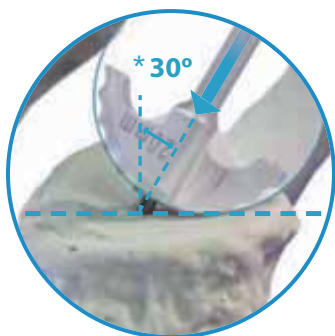
1. Use the **Drill Guide** to locate the intended implant position on the glenoid surface. Position the **Drill Guide** central to the inferior aspect of the glenoid lesion. Place the tip of the **Guide Pin** into the **Drill Guide** and advance the **Guide Pin** into the bone to the depth of the single etch mark using a cannulated power drill. The **Guide Pin** will be positioned slightly offset posteriorly. This is normal for the system as the **Reamer** begins to cut anterior first.



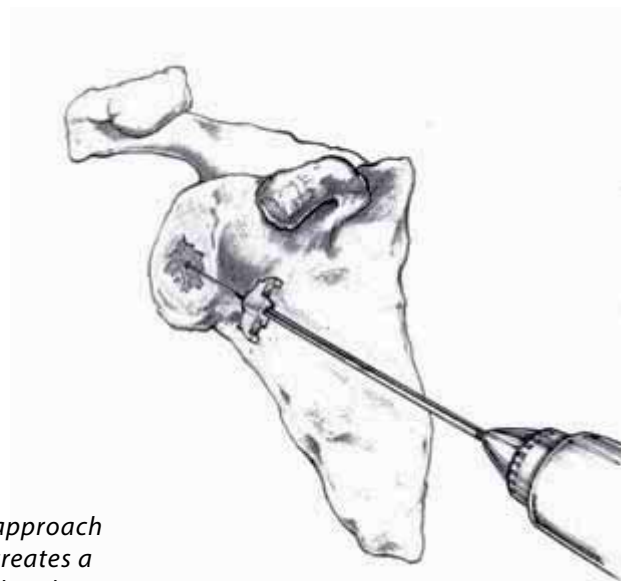
** This sets up angled approach for spherical reaming*



2. Introduce the **Inferior Glenoid Reamer** over the **Guide Pin** and carefully advance under power until the **Guide Pin** stops at the back of the **Proximal Reamer** window. Be sure to ream and visually check the depth of the reamer using the **Inferior Glenoid Trial** to help avoid posterior wall blowout.



** Angled approach & ream creates a spherical socket*

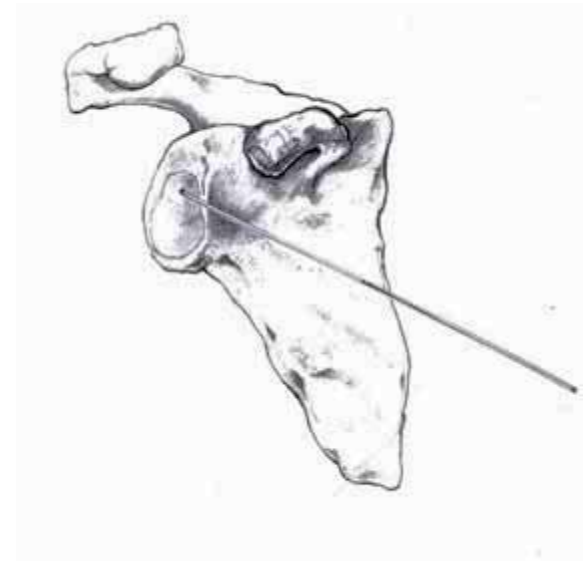


3. Position the slotted **Inferior Glenoid Trial** over the **Guide Pin** and confirm that the trial is flush or slightly recessed to the remaining glenoid fossa. Position the **Inferior Glenoid Trial** and place the **Flexible Peg Drill** into the central hole. Advance the **Flexible Peg Drill** to the stop to make the tunnel for the peg of the **Glenoid Component**.

**If using the Partial Glenoid Component only, proceed to Step 7*



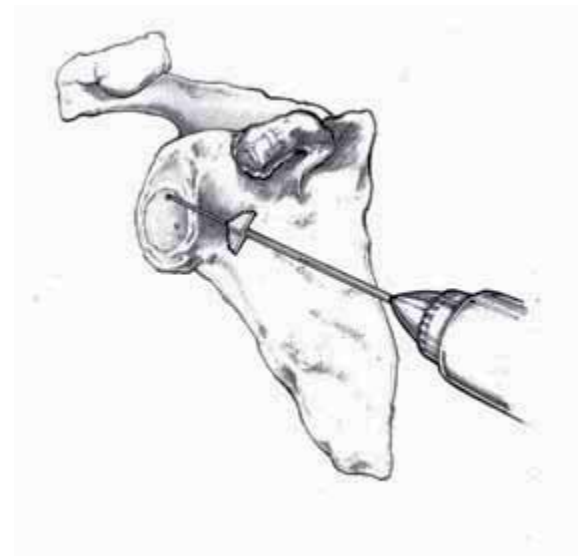
4. If using the larger **Double Glenoid**, place the **Inferior Glenoid Trial** in its proper orientation. Advance the **Guide Pin** into the superior hole of the trial and drill to the proximal line of the double etch mark using a cannulated powered drill.



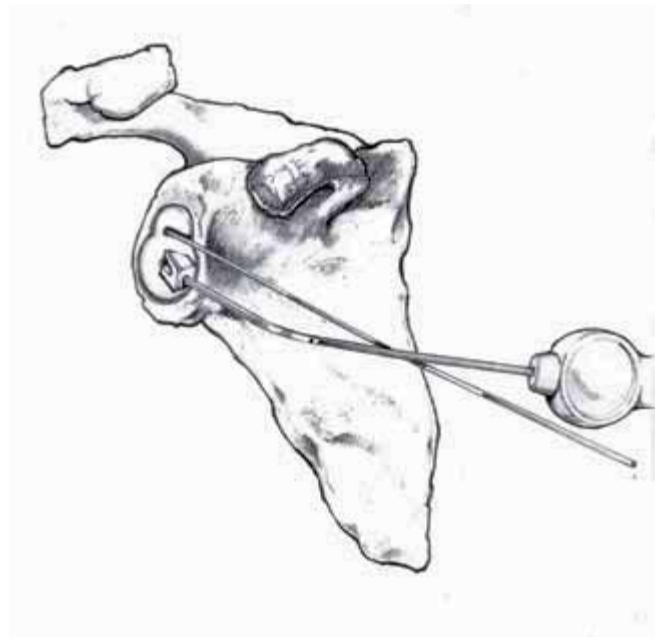
5. Introduce the **Superior Glenoid Reamer** over the **Guide Pin** and advance under power until the **Superior Glenoid Reamer** stops at the back of the **Proximal Reamer** window. Be sure to ream with caution and check the depth of the reamer to avoid posterior wall blowout. Position the **Double Glenoid Trial** and advance the **Flexible Peg Drill** into both central holes of the **Trial** to make bone tunnels for the **Double Glenoid Component** pegs.



Flexible Peg Drill



6. Position the **Double Glenoid Trial** and confirm that the trial is flush or slightly recessed to the remaining glenoid fossa. Advance the **Peg Drill** to perform bone cuts for the **Glenoid Component** superior peg. Place the **Sizing Trial** into the defect that matches the offset profile of the **HemiCAP® Glenoid Implant**. Confirm the fit of the **Sizing Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Sizing Trial** is proud at the edge of the articular cartilage, re-ream the area until the **Sizing Trial** is flush or slightly recessed.



7. Use the **Angled Gouge** and mallet to create several cement channels around the periphery of the glenoid fossa to aid with cement fixation.



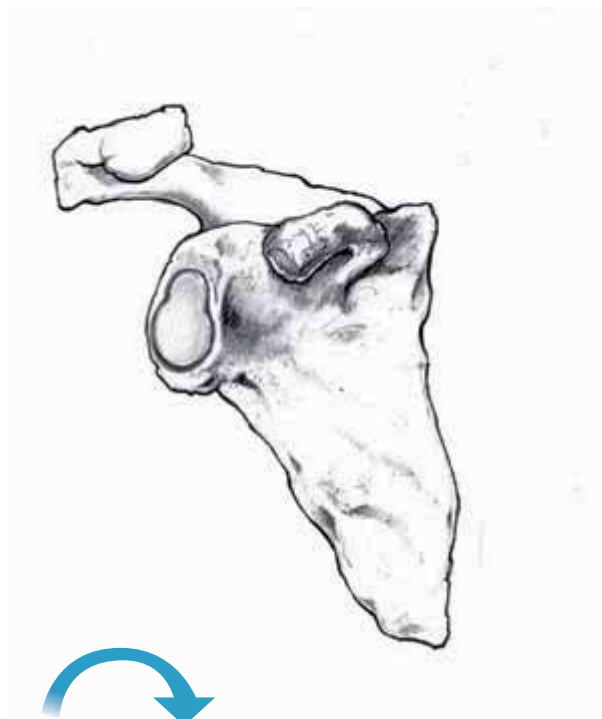
Angled Gouge

8. Apply a small amount of low-viscosity bone cement into the prepared glenoid surface. Using the **Cement Finger Cap**, apply pressure to the cement in the glenoid fossa to make sure the cement fills the peg holes and gouge channels.



Cement Finger Cap

9. Place the **HemiCAP® Glenoid Implant** into position and use the **Glenoid Impactor** to secure the glenoid implant into position making sure the implant fits flush or slightly recessed to the surrounding glenoid fossa. The **Glenoid Impactor** is created by sliding the **Slotted Impactor Tip** over the end of the **Angled Gouge**. Maintain firm pressure on the implant until the bone cement sets. Remove any excess bone cement.



Angled Gouge

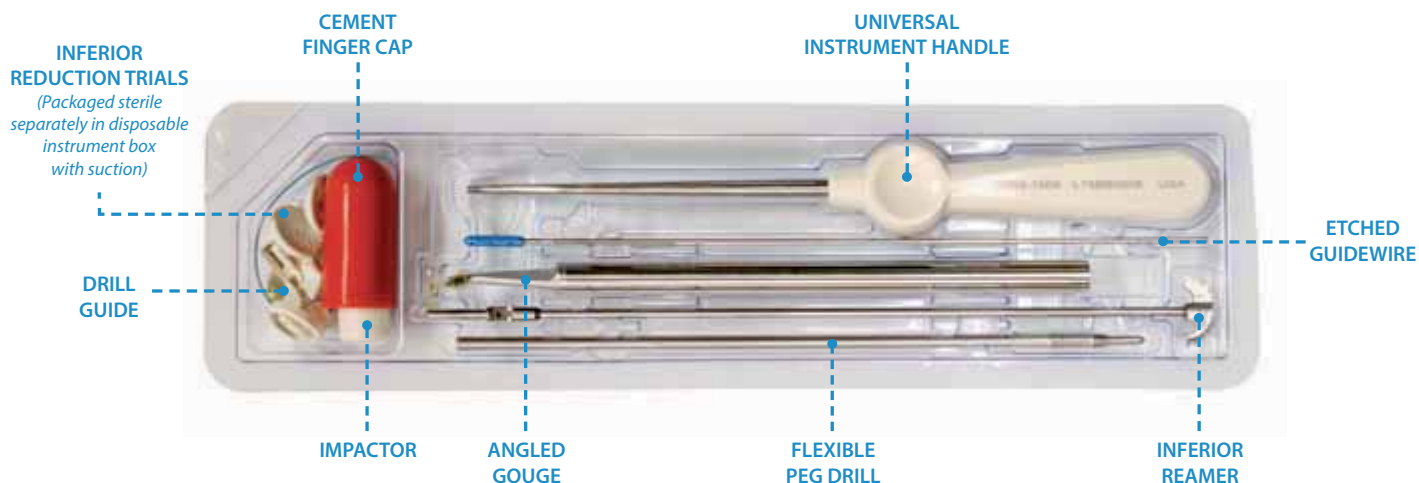
Tip



Impactor

Instrumentation (Inlay Glenoid Replacement)

Inferior Tray



Superior Tray



System Catalog

Glenoid Instrumentation System		Inlay Glenoid Component		Matching Ovo Head Diameters
G007-1400	2.0mm Glenoid Guide Pin (sterile)	Inferior Glenoid Component - Single		
G000-0100	Inferior Glenoid Instrument Kit (sterile, disposable)	G203-2010	19mm x 20mm Glenoid Comp. 1.0mm Offset	(58-54mm)
G000-0200	Superior Glenoid Instrument Kit (sterile, disposable)	G203-2015	19mm x 20mm Glenoid Comp. 1.5mm Offset	(52-54mm)
		Superior Glenoid Component - Double		
		G203-2515	20mm x 25mm Glenoid Comp. 1.0mm Offset	(58-54mm)
		G203-2520	20mm x 25mm Glenoid Comp. 1.5mm Offset	(52-44mm)



Total Shoulder Arthroplasty



Ovo / Glenoid

KEY FEATURES:

Bone & tissue sparing preserves future primary arthroplasty

Ovoid HemiCAP® shape matches humeral head geometry

*Anatomic head & inlay glenoid provides
best fit scenario*

Description

The HemiCAP® Contoured Articular Prosthetic incorporates an articular resurfacing component and a taper post component that mate together via a morse taper interlock to provide stable and immobile fixation of the implant and stress bearing contact at the bone/prosthetic interface.

Materials

Articular Resurfacing Component:	Cobalt-Chromium Alloy (Co-Cr-Mo)
Undersurface Coating:	Titanium (CPTi)
Taper Post:	Titanium Alloy (Ti-6Al-4V)

Indications

For the reconstruction of painful and/or severely disabled shoulder joints resulting from post-traumatic degenerative disease or avascular necrosis. The humeral head and neck should be sufficient bone stock to support loading. The rotator cuff should be intact or reconstructable. The device is a single use implant intended to be used with bone cement.

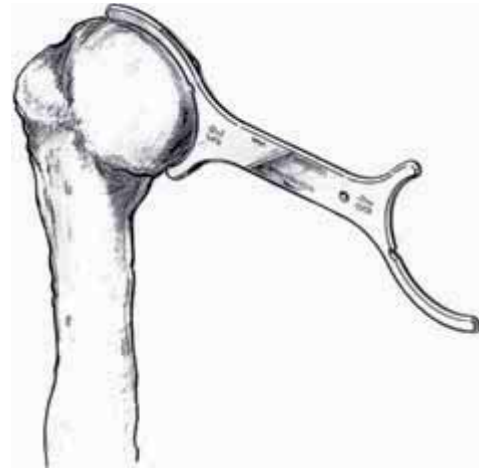
HemiCAP® System Components

- Cobalt Chrome Component
(Ovoid shapes, 6 offset choices)
- Ti Plasma Spray Undercoating
- Morse Taper:
Interlocks the two components
- Titanium Fixation Component
(Cannulated, Bead blasted)

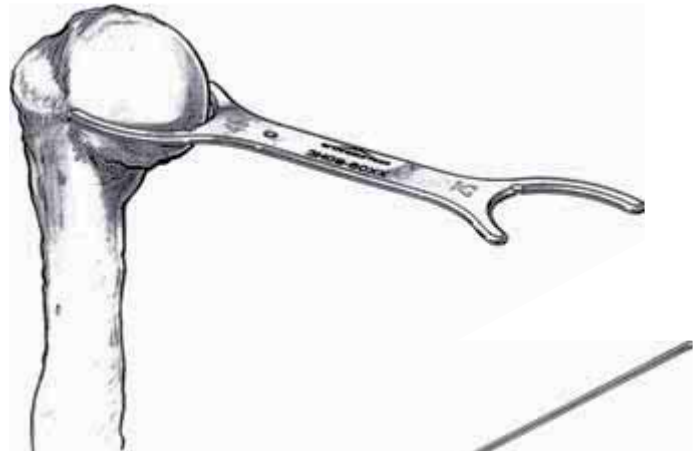


Surgical Technique (Ovo)

1. Remove all osteophytes around the humeral head using a 3/4 inch osteotome and/or rongeur. There should be a smooth transition from the humeral neck to the humeral head. Use the **Reduction Trial** to ascertain that all osteophytes have been adequately removed.



2. Place the appropriate **Mapping Templates** over the articular surface and map the surface in both superior/inferior and anterior/posterior planes. Utilize the **Templates** to obtain the superior/inferior diameter and anterior/posterior diameter that best replicate the anatomy. Use the **Sizing Card** to record the diameters. The **Surface Reamer** will be selected based on the anterior/posterior value. Place the **Reduction Trial** onto the humeral head to verify the **Reduction Trial** size and placement.

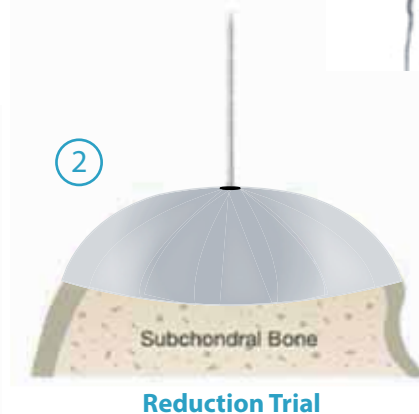
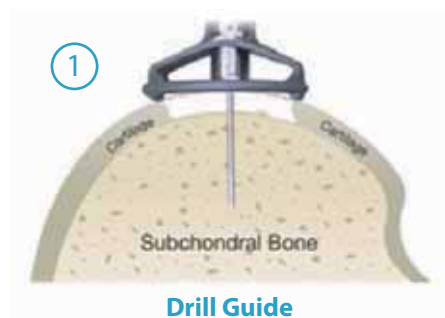


*Note: The **Surface Reamer** and/or **Drill Guide** may also be used to assess correct pin location.*

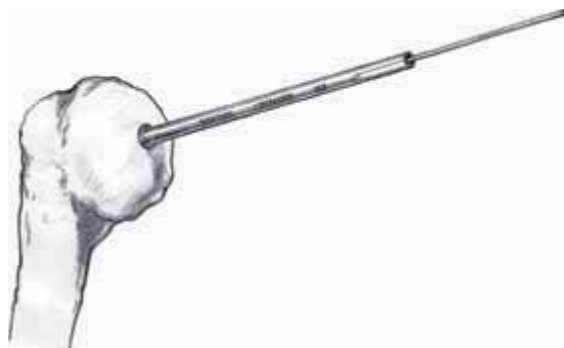
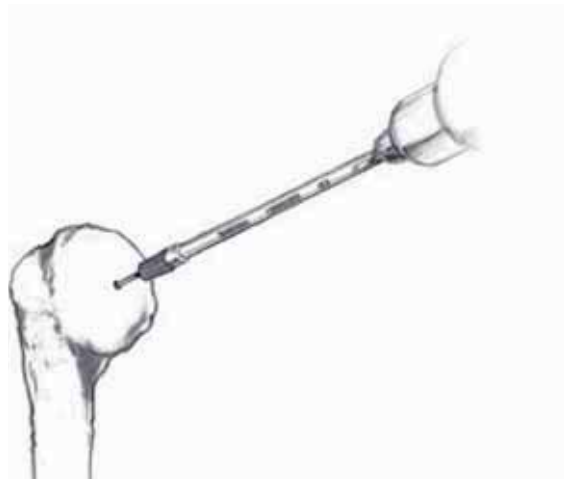
3. Locate the **Guide Pin** on head using option 1, 2, or 3 (see below). Place the **2.5 mm Guide Pin** into a cannulated powered drill and secure at the etch marking on the **Guide Pin**. Advance the **Guide Pin** into the bone with care to avoid penetrating through the lateral humeral cortex.



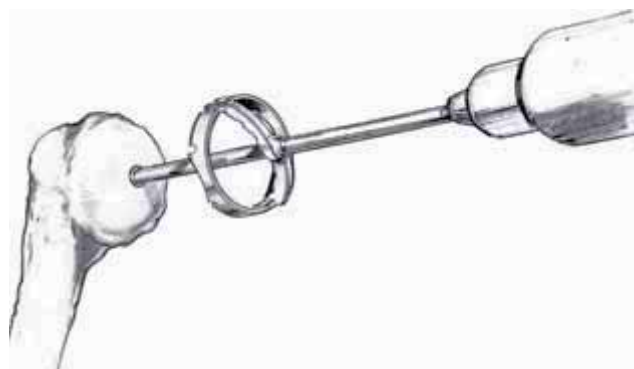
Options:



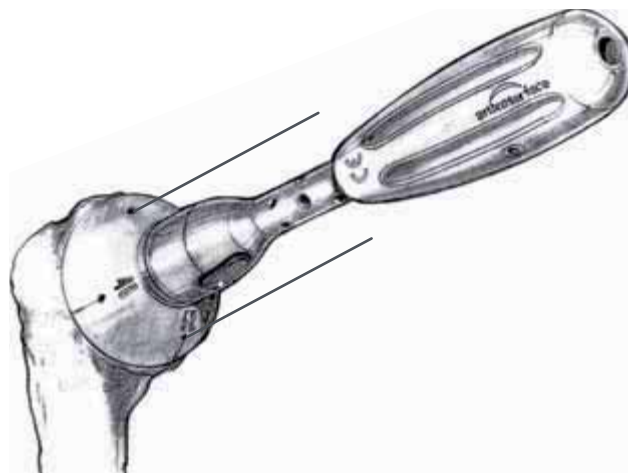
4. Using a cannulated powered drill, advance the **Centering Shaft** over the **Guide Pin** until the distal shoulder of the **Centering Shaft** marking is at the height of the articular surface. The **Centering Shaft** can be placed slightly proud to the surface to compensate for a flattened humeral head. The shoulder of the **Centering Shaft** sets the peak height representing the location of the crown of the implant.



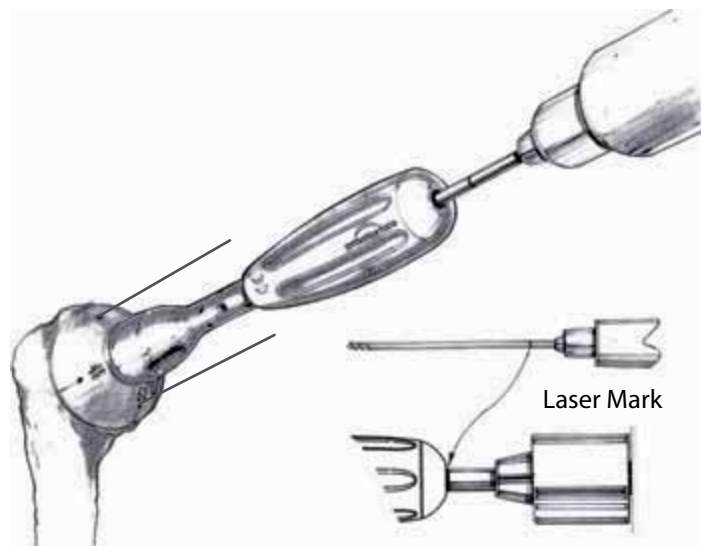
5. Using the **Ovo Reamer** that matches the anterior/posterior value, advance the **Ovo Reamer** over the **Centering Shaft** until it reaches the stop on the **Centering Shaft**. If using an **Inlay Glenoid Component**, repeat using the **Crown Reamer** to provide additional access for the **Glenoid** instruments. Be sure the **Ovo Reamer** is started before engaging the humeral head.



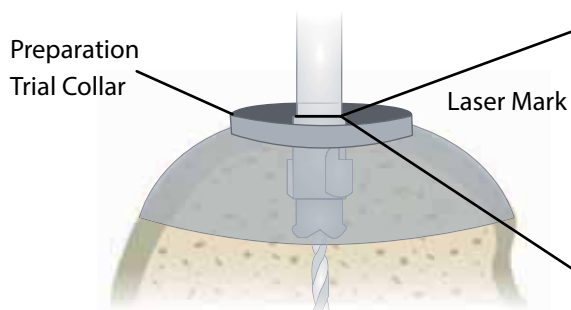
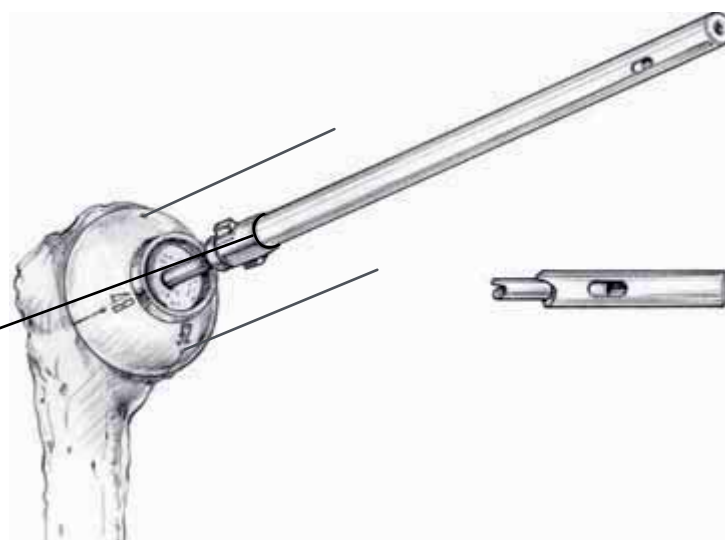
6. Place the appropriate **Reduction Trial** onto the prepared humeral surface and perform a range of motion evaluation. Assemble the **Guide Handle** onto the **Preparation Trial** and secure the **Preparation Trial** into position using at least two **Short Guide Pins**. The pins are critical, keeping the trial stable so that the correct orientation of the final implant can be maintained.



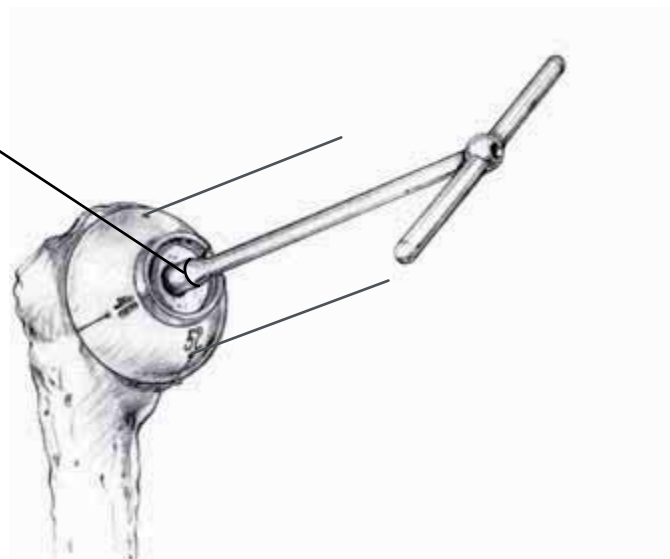
7. With the **Preparation Trial** fixed in place, insert the **Pilot Drill** through the center of the **Guide Handle** and advance until the laser mark indicated on the **Pilot Drill** meets the back of the handle. Leave the **Pilot Drill** in place and unscrew and remove the **Guide Handle**.



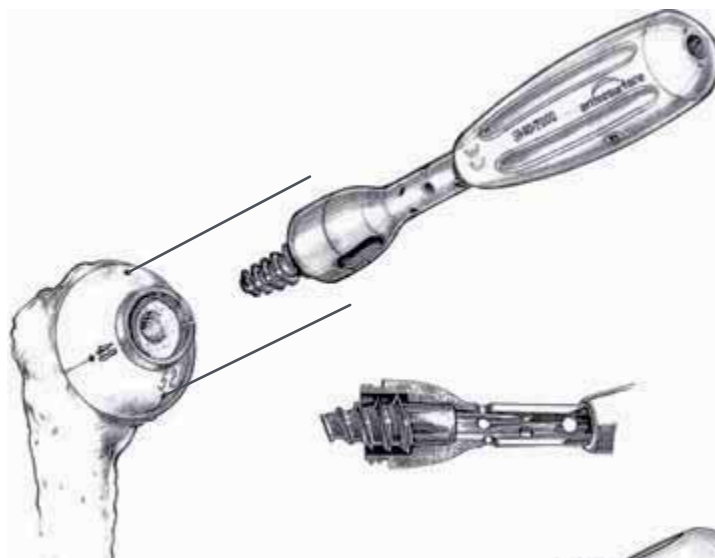
8. Advance the **Step Drill** over the **Pilot Drill** until the proximal shoulder of the **Step Drill** is even with the height marker on the **Preparation Trial** collar.



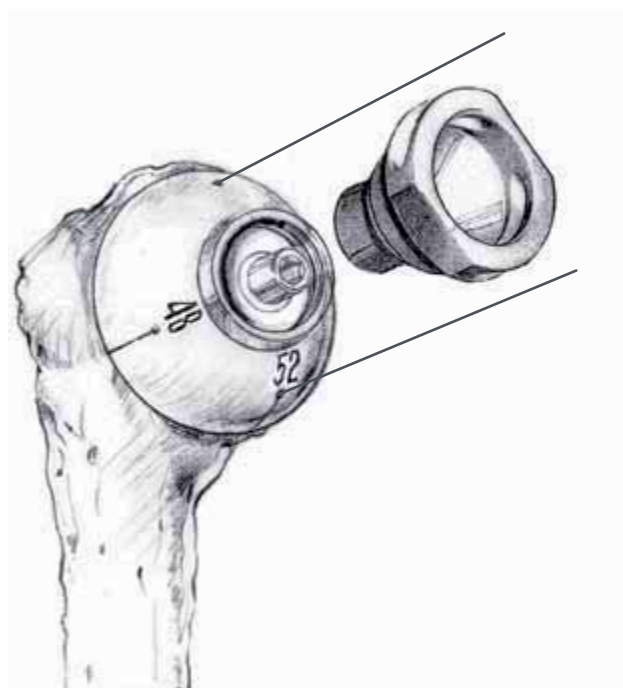
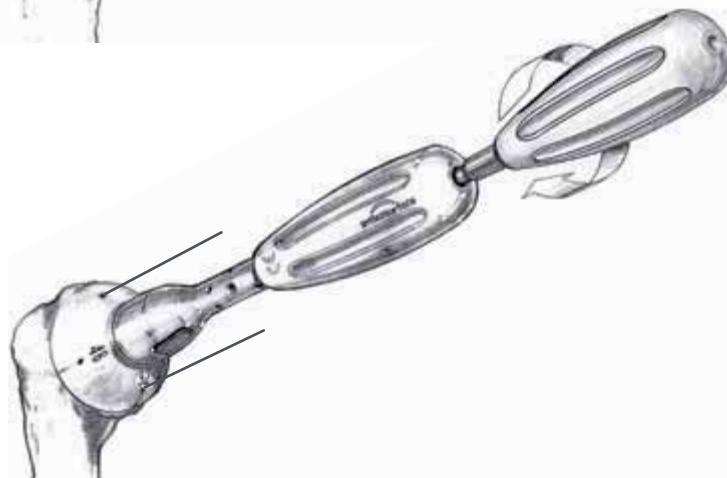
9. Advance the **Tap** over the **Pilot Drill** until the laser mark on the **Tap** is even with the height marker on the **Preparation Trial** collar. Remove the **Tap** and **Pilot Drill**.



10. Prior to inserting the **Taper Post**, thoroughly cleanse the pilot hole of any debris and inject the cement in a retrograde fashion from the end of the hole upwards. Load the **Taper Post** into the distal end of the **Guide Handle** and attach the **Guide Handle** to the **Preparation Trial**. Place the **Hex Driver** through the **Guide Handle** and advance the **Taper Post** until the stop in the shaft of the **Hex Driver** comes in contact with the back of the **Guide Handle**. Be careful NOT to advance the screwdriver once it contacts the handle as it will move the screw in and away from the **Morse Taper**.



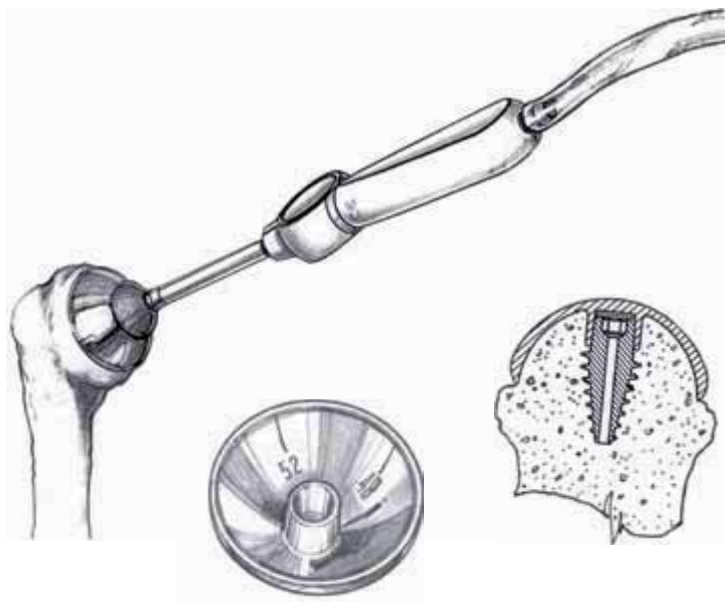
11. Use the **Alignment Gauge** to ensure that the **Taper Post** is seated at the proper depth. The **Alignment Gauge** is inserted into the **Preparation Trial**. The **Gauge** should meet resistance from the **Taper Post** and be flush with the edge of the **Preparation Trial**. If the **Gauge** is sitting proud then leave it in place and use the **Hex Driver** to rotate it flush with the **Trial**. If the Alignment Gauge does not connect with the **Taper Post** then the **Taper Post** has been inserted too far into the bone. To address this situation, rotate the **Taper Post** counterclockwise and check placement with the **Alignment Gauge**. Place the **Reduction Trial** into the defect that matches the offset profile of the chosen **HemiCAP® Articular Component**. Confirm the fit of the **Reduction Trial** so that it is congruent with the edge of the surrounding articular surface or slightly recessed. If the **Reduction Trial** is proud at the edge of the articular cartilage, re-ream the area until the **Reduction Trial** is flush or slightly recessed.



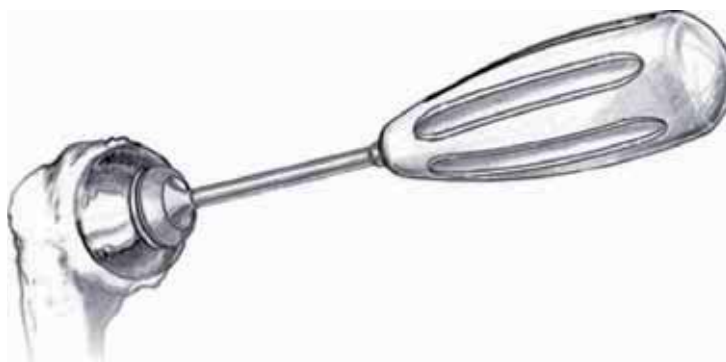
IF PERFORMING THE GLENOID:

Proceed to Step 1 in Chapter Two

12. Prior to placing the **Ovo Resurfacing Component** on the **Implant Holder**, make sure that sufficient suction is present to hold the device onto the distal suction cup. Align the **Ovo Resurfacing Component** on the **Implant Holder** with the etch mark inline with the superior offset of the **Ovo Resurfacing Component**. Use the **Implant Holder** mark to align the implant in the proper orientation and insert onto the taper of the **Taper Post**.

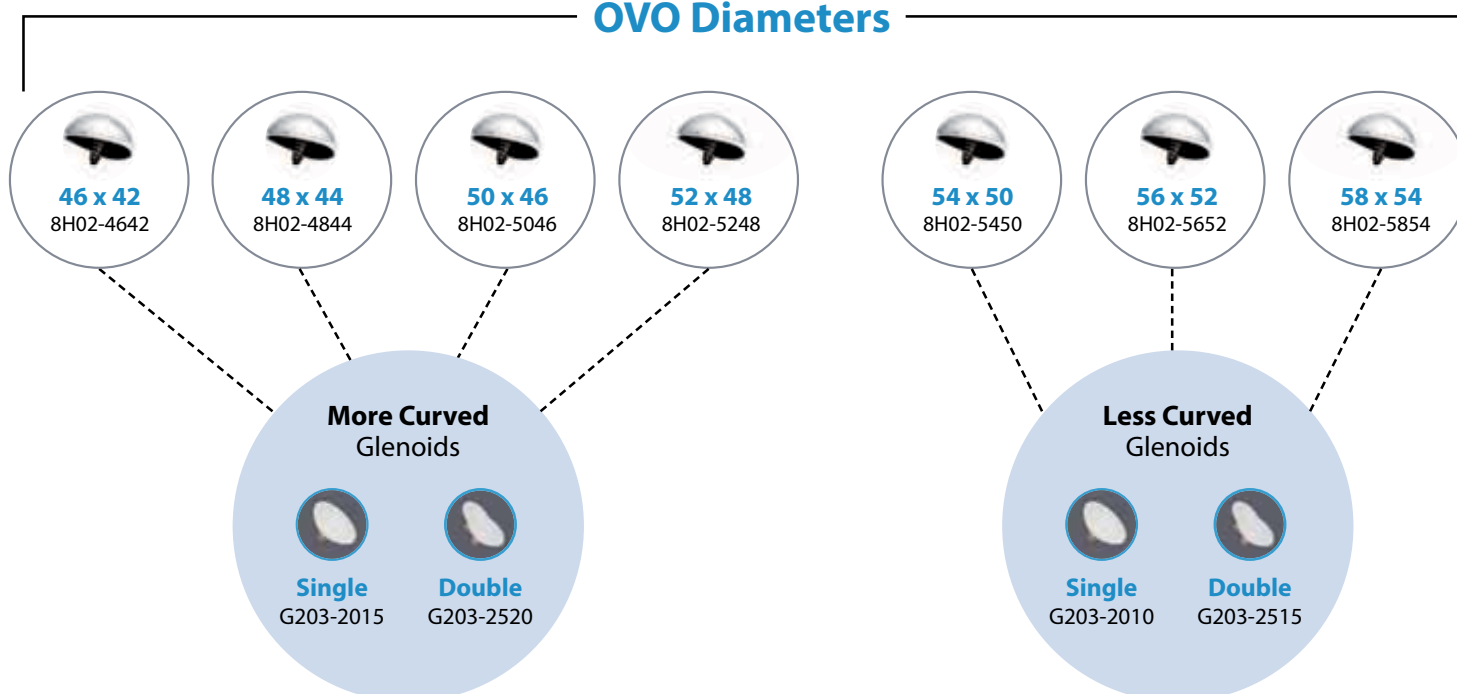


13. Firmly mallet the **Impactor** until the **Ovo Resurfacing Component** is completely seated onto the **Taper Post**.



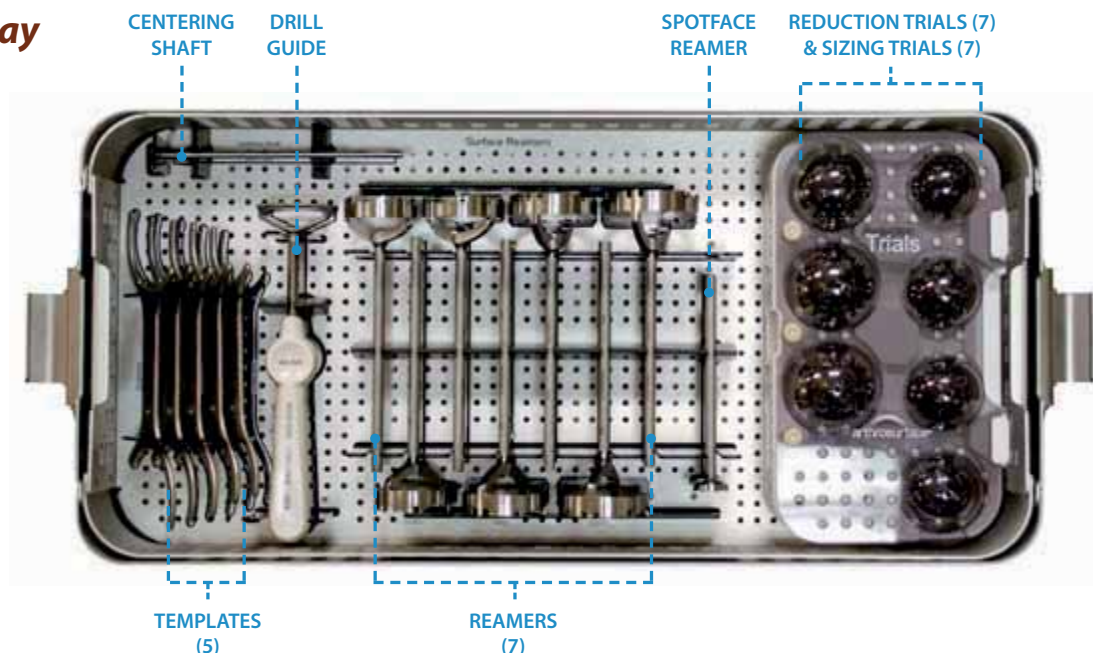
Matching Ovo Diameters to Appropriate Glenoid

OVO Diameters

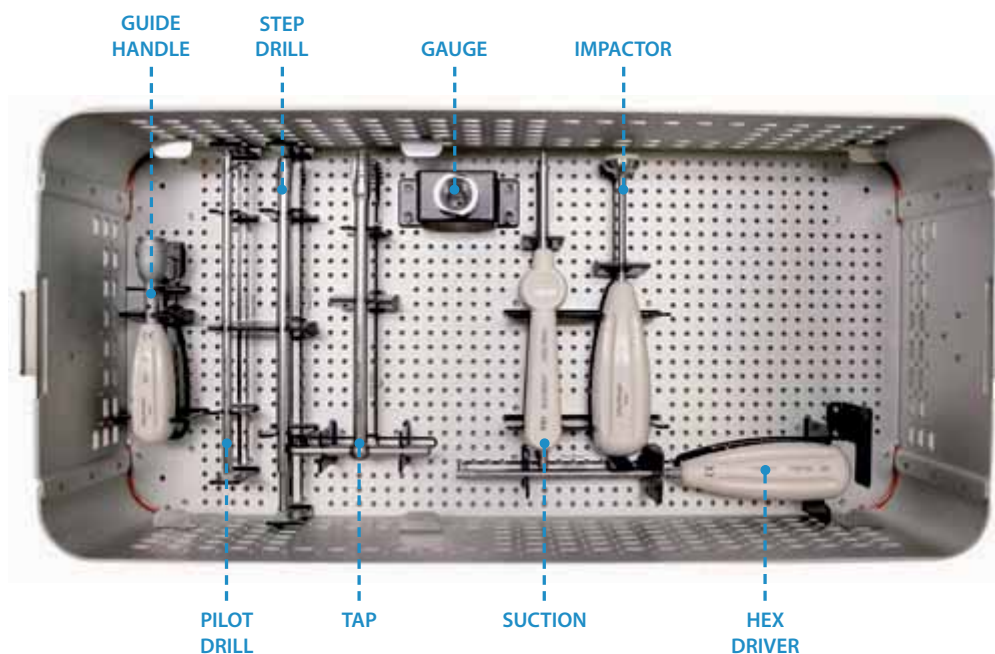


Instrumentation (Ovo)

Upper Tray



Lower Tray



System Catalog (Ovo)

Instrumentation System

8000-5000	Ovo Instrumentation Kit
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Taper Post (Fixation Component)

8156-0032	15.6mm x 32mm (for Ovo only) includes 2.5mm guide wire, 2.0mm short guide pins and taper cleaner
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Ovo Humeral Articular Components

8H02-4642	46mm x 42mm Offset
8H02-4844	48mm x 44mm Offset
8H02-5046	50mm x 46mm Offset
8H02-5248	52mm x 48mm Offset
8H02-5450	54mm x 50mm Offset
8H02-5652	56mm x 52mm Offset
8H02-5854	58mm x 54mm Offset



Warnings

Improper selection, placement, positioning, alignment, and fixation of the implant components may reduce the service life of the prosthetic components. Inadequate preparation and cleaning of the implant components mating surfaces may result in improper fixation of the device. Improper handling of the implants can produce scratches, nicks or dents that may have adverse clinical effects on mating joint surfaces. Do not modify implants. The surgeon shall be thoroughly familiar with the implants, instruments, and surgical technique prior to performing surgery.

When defining offsets of articular surfaces, care should be taken to ensure that instruments are properly aligned. When placing implant, carefully trim articular cartilage debris or osteophytes around margin of implant. Remove bone particles and lavage thoroughly. To ensure mechanical interlock of the Taper Post and implant, carefully clean Taper Post taper with provided instruments. All drilling or reaming should be done at slowest speeds possible with vigorous lavage to minimize heat effects to adjacent bone and cartilage tissues.

Accepted practices in post operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post operative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.

Precautions

HemiCAP® implants are intended to be fitted and installed with the HemiCAP® instrument set. Use of instruments from other systems may result in improper implant selection, fitting, and placement which could result in implant failure or poor clinical outcome. The HemiCAP® instrument set should be regularly inspected for any signs of wear or damage. Do not reuse implants.

Possible Adverse Effects

- 1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed of similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
- 2) Infection or allergic reaction.
- 3) Loosening, migration or loss of fixation of implant.
- 4) Fretting and crevice corrosion can occur at the interface between the implant components.
- 5) Fatigue fracture of the implants as a result of bone resorption around the implant components.
- 6) Wear and damage to the implant articulating surface.
- 7) Wear and damage to the adjacent and opposed articular cartilage surfaces or soft tissue support structures.
- 8) Intraoperative or postoperative bone fracture.



Asymmetrical

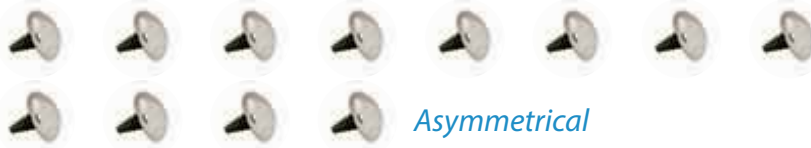
40



Symmetrical

Asymmetrical

35



Symmetrical

Asymmetrical

30



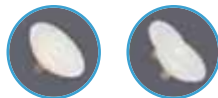
Symmetrical

25



Symmetrical

GRS



★ *The HemiCAP^{GRS} glenoid component is currently not available in all markets.*

This product is covered by one or more of U.S. Patent Nos. 6,520,964;
6,610,067; 6,679,917 and other patents pending.
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